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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,718	10/17/2003	Jack D. Lemmon	M190.143.101	1756

7590 08/24/2005

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Tate

Office Action Summary	Application No. 10/688,718	Applicant(s) LEMMON, JACK D.	
	Examiner Bruce E. Snow	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 38 is/are pending in the application.
- 4a) Of the above claim(s) 7, 14, 29 and 31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-13, 15-21, 25-28 and 30 is/are rejected.
- 7) ☒ Claim(s) 22-24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/04/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's amendments and arguments filed 6/22/05 have been fully considered. Applicant's amendment overcame the rejection under 35 U.S.C. 102(b) as being clearly anticipated by Rhee (6,350,281).

Applicant's argues that the sizer of Love et al fails to meet the limitation, "*wherein the annular wall forms a plurality of extremities adapted to be inwardly deflected*" which is not persuasive. Love et al teaches "the material preferably has sufficient rigidity to maintain its shape during sizing procedure, but also a degree of malleability to make it easy to insert into.. the valve root without damaging the tissue." It is the Examiner's position that malleability to make it easy to insert describes that the extremities can be adapted to be inwardly deflected. Additionally, the materials taught by Love are fully capable of being inwardly deflected. Finally, applicant has failed to describe what degree of force is necessary to inwardly deflect the extremities giving the limitation no degree of patentability.

Allowable Subject Matter

Claim 38 is allowed.

Claims 22-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6, 8-11, 15-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated Buchanan (2002/017384).

Buchanan teaches a flexible sizer body for evaluating a valve annulus to determine a size of a prosthetic heart valve to be sewn to the valve annulus during heart valve replacement surgery, the prosthetic heart valve including an annular extension

having a first flexibility and a sewing ring having a second flexibility, the flexible sizer body comprising:

- an outer ring 44 characterized by the absence of a cloth cover; and
- an annular wall 10 (see at least figures 5-6) coupled to and extending from the outer ring, wherein the annular wall forms a plurality of extremities adapted to be inwardly deflected.

Claims 1-6, 8-10, 12-13, 15-21, 25-28, 30 are rejected under 35 U.S.C. 102(b) as being clearly anticipated Love et al (2002/0020074).

Love et al teaches a flexible sizer body for evaluating a valve annulus to determine a size of a prosthetic heart valve to be sewn to the valve annulus during heart valve replacement surgery, the prosthetic heart valve including an annular extension having a first flexibility and a sewing ring having a second flexibility, the flexible sizer body comprising:

- an outer ring 1 characterized by the absence of a cloth cover; and
- an annular wall 2 coupled to and extending from the outer ring, wherein the annular wall forms a plurality of extremities adapted to be inwardly deflected (see at least paragraph 017).

Regarding claim limitation directed to the heart valve such as claims 3-4, the heart valve is not positively claimed.

The Examiner notes that applicant has only defined the flexibility of the annular wall to be substantially similar to the flexibility of the annular extension of the heart

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valve, however, fails to define the flexibility of the heart valve. It is well known in the art that the flexibility of an annular extension of various heart valves can range from little flexibility (rigid) or can have a greater degree of flexibility. It is the Examiner's position that any degree of flexibility (including greater than or equal to no flexibility) would fulfill this undefined limitation.

Regarding claim 9, the diameter of the sewing ring is undefined.

Regarding at least claim 15, the body inherently has a variable flexibility. Again, the heart valve flexibility is undefined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Love et al (2002/0020074).

Love et al teaches the sizer as described above including sizer can be made of a biocompatible thermoplastic material. However, Love et al fails to specifically teach the outer ring and annular wall are each formed of at least one of the group consisting of santoprene, silicon, and polyurethane. It would have been obvious to one having ordinary skill in the art to have selected at least one of the claimed materials, such as

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polyurethane, because they are well known in the art for their biocompatibility and ease of manufacture as a thermoplastic.

Claims 1-6, 8-13, 15-21, 25-28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhee (6,350,281) in view of Love et al (2002/0020074).

Rhee teaches a flexible sizer body for evaluating a valve annulus to determine a size of a prosthetic heart valve to be sewn to the valve annulus during heart valve replacement surgery, the prosthetic heart valve including an annular extension having a first flexibility and a sewing ring having a second flexibility, the flexible sizer body comprising:

an outer ring 16 characterized by the absence of a cloth cover; and an annular wall 18 coupled to and extending from the outer ring, the annular wall having a flexibility substantially similar to the first flexibility of the annular extension of the prosthetic heart valve.

However, Rhee fails to teach the annular wall forms a plurality of extremities. Love et al teaches a sizer having the claimed configuration. It would have been obvious to one having ordinary skill in the art to have utilized the claimed configuration taught by Love et al with the annular wall of Rhee such that the sizer *"correspond to the geometry of the normal valve leaflet anatomy (paragraph 0005 of Love et al)"* or by better *"matching the artificial heart configuration, the sizer is able to 'mimic' more accurately how the artificial heart valve will be received in the valve annulus for sewing (4:1-4 of Rhee)"*.

The Examiner notes that applicant has only defined the flexibility of the annular wall to be substantially similar to the flexibility of the annular extension of the heart valve, however, fails to define the flexibility of the heart valve. It is well known in the art that the flexibility of an annular extension of various heart valves can range from little flexibility (rigid) or can have a greater degree of flexibility. It is the Examiner's position that any degree of flexibility (including greater than or equal to no flexibility) would fulfill this undefined limitation. The Examiner notes claim 13 teaching the annular wall 18 is substantially rigid and claim 14 teaching the annular wall is resilient.

Regarding at least claim 8, see 3:55-58.

Regarding at least claim 4, the annular wall is interpreted as being a stent.

Regarding claim 10, wherein the outer ring and the annular wall are each at least partially formed of an elastomeric material, note 5:24-27 teaching the outer ring is **"made from resilient material, such as a soft polymer, so as to be compressible and flexible"** which is interpreted as being an elastomeric material. Further note, 6:58-64 teaching the annular wall can be resilient and formed as a one-piece design with the outer ring, therefore, also being an elastomeric material.

Regarding at least claim 15, the body inherently has a variable flexibility. Again, the heart valve flexibility is undefined.

Regarding claim 18, "parabolic", the annular is interpreted as including element 14; see at least 7:1-4.

Regarding claims 11 and 24, Rhee teaches the sizer as described above, however, fails to specifically teach the outer ring and annular wall are each formed of at least one of the group consisting of santoprene, silicon, and polyurethane. Again, Rhee teaches the outer ring is “***made from resilient material, such as a soft polymer, so as to be compressible and flexible***” which is interpreted as being an elastomeric material. Further note, 6:58-64 teaching the annular wall can be resilient and formed as a one-piece design with the outer ring, therefore, also being an elastomeric material. It would have been obvious to one having ordinary skill in the art to have selected at least one of the claimed materials because they are well known in the art for their biocompatibility and use for heart valve or sizer construction; note 6:64-67.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

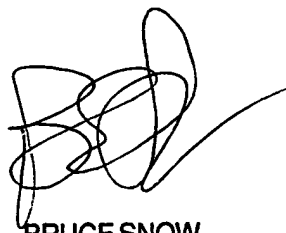
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW
PRIMARY EXAMINER